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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,346	01/14/2004	Heinrich Kladders	1/1447	3492
28501	7590	06/04/2007	EXAMINER	
MICHAEL P. MORRIS			MATTER, KRISTEN CLARETTE	
BOEHRINGER INGELHEIM CORPORATION			ART UNIT	PAPER NUMBER
900 RIDGEBURY ROAD				3771
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RIDGEFIELD, CT 06877-0368				
MAIL DATE		DELIVERY MODE		
		06/04/2007		
		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/757,346	KLADDERS ET AL.
	Examiner	Art Unit
	Kristen C. Matter	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 May 2007.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-10 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5,947,118) in view of Datta et al. (US 5,871,010) and further in view of Bartels et al. (US 5,472,143).

As to claims 1 and 5, Hochrainer et al. disclose an inhaler for the administration of a pharmaceutical composition comprising a mouthpiece (12), an air channel opening into the mouthpiece and a chamber (9) with an air inlet channel wherein the inhaler is capable of receiving a capsule with a composition (see Figure 6). Hochrainer et al. does not disclose at least part of the inner surface of the mouthpiece and/or of the air channel and/or optionally the chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 microns. However, Datta et al. teach an inhaler apparatus with a modified surface for enhanced release of dry powders. Datta et al. disclose the surface of the substrate and the mouthpiece as having elevations and depressions with a depth of one micron to about 2.5 microns (column 2, lines 15-44), which meets the claimed range of 0.1 to 100 microns. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. with the depressions taught by Datta et al. in order to decrease the area of contact between the selected medicaments so that medicament particles do not stick to

the inside surface of the mouthpiece. The modified Hochrainer and Datta et al. reference is silent as to the process for forming the elevations/depressions. Bartels et al. disclose an atomizing nozzle for use in an inhaler in which the depressions forming the nozzle outlets are formed from well-known microforming techniques including chemical etching, laser, photo-resist, or other engraving techniques (column 4, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used chemical etching (a microtechnology and subtractive treatment), for example, to produce the depressions in the modified device of Hochrainer et al. and Datta et al. in order to produce readily reproducible and accurate depressions in the mouthpiece on a micro-scale.

As for claim 2, Datta et al. is silent as to the percentage of the interior surfaces having depressions. However, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have used microtechnology to produce depressions over at least 20% of the inner surfaces in order to deliver a maximum amount of medicament to the user without having the particles stick to the inside surfaces of the inhaler.

As for claim 3, Datta et al. disclose the elevations and depressions are separated by spacings of 2 microns, which reads inside the range from 0.1 to 200 microns.

As for claim 4, Datta et al. has taught an inhaler with inner surfaces being made with polycarbonate (column 7, line 65), for example, which is one of the claimed materials.

As for claims 6 and 7, Hochrainer et al. inherently disclose a Bernoulli inhaler. In addition, the applicant has admitted that Bernoulli inhalers are prior art (paragraph 3, lines 4-7). Hochrainer et al. disclose the inhaler comprising a capsule chamber (9), which is connected to the air channel opening in the mouthpiece.

In regards to claims 9 and 10, Hochrainer et al. disclose the inhaler as having a cutting device, which is fitted with at least two sharp spikes, the spikes are capable of being inserted through openings into the capsule chamber (column 3, lines 5-9). Hochrainer et al. continue to disclose an inhaler comprising a cup-shaped lower part 6 open at the top, a plate (8) that covers the opening of the lower part (6) and perpendicularly to which is formed the capsule chamber, a button (10) movable counter to a spring on the capsule chamber, comprising two sharp spikes for opening the capsule, an upper part (13) with the mouthpiece (12) and the air channel which connects the mouthpiece (12) to the capsule chamber (9) so as to be able to convey a powder or liquid or aerosol, and a lid, these elements being joined together by a common hinge element such that they can be moved back and forth relative to one another (column 3, lines 15-18).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. and Datta et al. and Bartels et al. and further in view of Kladders (US 4,889,114). The modified Hochrainer et al. reference has disclosed everything except the capsule chamber as having a diameter 1.1 to 2.5 times the capsule diameter and a length 1.02 to 2 times the length of the capsule. However, Hochrainer et al. has taught that the capsule chamber needs to have a diameter large enough to hold the capsule (column 1, lines 19-21). In addition, Kladders discloses a similar powder inhaler with a capsule chamber (6) with a diameter 1.1 to 2.5 times the capsule diameter and a length 1.03 to 2 times the length of the capsule (column 2, lines 10-19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Hochrainer et al., Datta et al., and Bartels et

al. with the capsule chamber diameter and length as taught by Kladders so that the capsule fits in the chamber in order to be more effective during delivery for inhalation.

***Response to Arguments***

Applicant's arguments filed 5/8/2007 have been fully considered but they are not persuasive. Although the claims have been changed to now claim a process instead of an apparatus, the modified device has all of the structural limitations outlined in the claims. Bartel et al. disclose that the claimed processes (i.e., microtechnology, etching, etc.) were well known in the art and commonly used for producing depressions in the mouthpieces of inhaler devices at the time of the invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*KCM*  
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5/29/07